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#### INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 7: C12N 15/20, A61K 48/00,	A3	(1	1) International Publication Number:	WO 00/40273
A61P 31/12, 31/20	AS	(4	3) International Publication Date:	13 July 2000 (13.07.00)
(21) International Application Number: PCT/US (22) International Filing Date: 28 December 1999 (			(81) Designated States: CA, JP, US, Eur CY, DE, DK, ES, FI, FR, GB, PT, SE).	
(30) Priority Data: 60/115,403 8 January 1999 (08.01.99)	τ	US	Published With international search report.	
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(54) Title: TREATMENT OF VIRAL DISEASES USING		INT	ERFERON OMEGA EXPRESSING POL	/NUCLEOTIDE

#### (57) Abstract

The present invention provides a method of treating a viral disease comprising administering to a mammal a polynucleotide construct comprising a polynucleotide encoding  $IFN\omega$ . The polynucleotide construct of the present invention can be administered free from associated with transfection facilitating agents or as a complex with at least one or more cationic lipids.

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C. DOCUMI	ENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the	relevant passages	Relevant to claim No.
Υ	EP 0 170 204 A (BOEHRINGER INGE 5 February 1986 (1986-02-05) cited in the application page 3, line 6 -page 5, line 4 page 12, line 15 - line 24 page 34 -page 47; examples 1-5 page 53 -page 58; example 8 figure 11 page 32, line 15 - line 24 page 63, line 6 -page 64, line		1-32
X Furt	her documents are listed in the continuation of box C.	Patent family members are listed	in annex.
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Im ational Application No PCT/US 99/30843

Colorination DOCUMENTS CONSIDERED TO BE RELEVANT  Y RAZ EYAL ET AL: "Systemic immunological effects of cytokine genes injected into skeletal muscle." PROCEEDINGS OF THE NATIONAL ACADEMY OF SCIENCES OF THE UNITED STATES, vol. 90, no. 10, 1993, pages 4523-4527, XP002144215 1993 ISSN: 0027-8424 page 4523, 'Introduction' page 4525 - page 4526, 'Discussion'  A W0 96 17063 A (VICAL INC) 19-23  MO 96 17063 A (VICAL INC) 19-23  DATABASE BIOSIS 'Online! 26 page 40, line 4 - line 21  A DATABASE BIOSIS 'Online! 26 page 40, line 4 - line 21  A DATABASE BIOSIS 'Online! 26 page 40, line 4 - line 21  A DATABASE BIOSIS 'Online! 26 page 40, line 4 - line 21  A DATABASE BIOSIS 'Online! 26 page 40, line 4 - line 21  A DATABASE BIOSIS 'Online! 26 page 40, line 4 - line 21  A DATABASE BIOSIS 'Online! 26 page 40, line 4 - line 21  A DATABASE BIOSIS 'Online! 30 page 40, line 4 - line 21  A DATABASE BIOSIS 'Online! 30 page 40, line 4 - line 21  A DATABASE BIOSIS 'Online! 30 page 40, line 4 - line 21  A DATABASE BIOSIS 'Online! 30 page 40, line 4 - line 21  A DATABASE BIOSIS 'Online! 30 page 50			PC1/US 99/30843
Y RAZ EYAL ET AL: "Systemic immunological effects of cytokine genes injected into skeletal muscle." PROCEEDINGS OF THE NATIONAL ACADEMY OF SCIENCES OF THE UNITED STATES, vol. 90, no. 10, 1993, pages 4523-4527, XPD02144215 1993 ISSN: 0027-8424 page 4523, 'Introduction' page 4525 - page 4526, 'Discussion'  A WO 96 17063 A (VICAL INC) 6 June 1996 (1996-06-06) page 4, line 18 - line 24 page 5, line 33 - line 36 page 40, line 4 - line 21  A DATABASE BIOSIS 'Online! BIOSCIENCES INFORMATION SERVICE, PHILADELPHIA, PA, US: 1994 KOKOREVA L N ET AL: "Clinico-morphological characterization and effectiveness of interferon therapy in patients with chronic hepatitis delta." Database accession no. PREV199497368940 XP002144216 abstract 8 ZHURNAL MIKROBIOLOGII EPIDEMIOLOGII I IMMUNOBIOLOGII, no. 1, 1994, pages 55-59, ISSN: 0372-9311  A DATABASE BIOSIS 'Online! BIOSCIENCES INFORMATION SERVICE, PHILADELPHIA, PA, US: 17 December 1998 (1998-12-17) AULT A: "FDA approves two new hepatitis therapies." Database accession no. PREV199900076805 XP002144217 abstract 8 LANCET (NORTH AMERICAN EDITION), vol. 352, no. 9145, 17 December 1998 (1998-12-17), page 1996 ISSN: 0099-5355			
effects of cytokine genes injected into skeletal muscle." PROCEEDINGS OF THE NATIONAL ACADEMY OF SCIENCES OF THE UNITED STATES, vol. 90, no. 10, 1993, pages 4523-4527, XP002144215 1993 ISSN: 0027-8424 page 4523, 'Introduction' page 4525 - page 4526, 'Discussion'  A W0 96 17063 A (VICAL INC) 6 June 1996 (1996-06-06) page 4, line 18 - line 24 page 5, line 33 - line 36 page 40, line 4 - line 21  A DATABASE BIOSIS 'Online! BIOSCIENCES INFORMATION SERVICE, PHILADELPHIA, PA, US; 1994 KOKOREVA L N ET AL: "Clinico-morphological characterization and effectiveness of interferon therapy in patients with chronic hepatitis delta." Database accession no. PREV199497368940 XP002144216 abstract 8 ZHURNAL MIKROBIOLOGII EPIDEMIOLOGII I IMMUNOBIOLOGII, no. 1, 1994, pages 55-59, ISSN: 0372-9311  A DATABASE BIOSIS 'Online! BIOSCIENCES INFORMATION SERVICE, PHILADELPHIA, PA, US; 17 December 1998 (1998-12-17) AULT A: "FDA approves two new hepatitis therapies." Database accession no. PREV199900076805 XP002144217 abstract & LANCET (NORTH AMERICAN EDITION), vol. 352, no. 9145, 17 December 1998 (1998-12-17), page 1996 ISSN: 0099-5355	Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
6 June 1996 (1996-06-06) page 4, line 18 - line 24 page 5, line 33 - line 36 page 40, line 4 - line 21  A DATABASE BIOSIS 'Online! BIOSCIENCES INFORMATION SERVICE, PHILADELPHIA, PA, US; 1994 KOKOREVA L N ET AL: "Clinico-morphological characterization and effectiveness of interferon therapy in patients with chronic hepatitis delta." Database accession no. PREV199497368940 XP002144216 abstract & ZHURNAL MIKROBIOLOGII EPIDEMIOLOGII I IMMUNOBIOLOGII, no. 1, 1994, pages 55-59, ISSN: 0372-9311  A DATABASE BIOSIS 'Online! BIOSCIENCES INFORMATION SERVICE, PHILADELPHIA, PA, US; 17 December 1998 (1998-12-17) AULT A: "FDA approves two new hepatitis therapies." Database accession no. PREV199900076805 XP002144217 abstract & LANCET (NORTH AMERICAN EDITION), vol. 352, no. 9145, 17 December 1998 (1998-12-17), page 1996 ISSN: 0099-5355	Y	effects of cytokine genes injected into skeletal muscle." PROCEEDINGS OF THE NATIONAL ACADEMY OF SCIENCES OF THE UNITED STATES, vol. 90, no. 10, 1993, pages 4523-4527, XP002144215 1993 ISSN: 0027-8424 page 4523, 'Introduction'	1-32
BIOSCIENCES INFORMATION SERVICE, PHILADELPHIA, PA, US; 1994 KOKOREVA L N ET AL: "Clinico-morphological characterization and effectiveness of interferon therapy in patients with chronic hepatitis delta." Database accession no. PREV199497368940 XP002144216 abstract & ZHURNAL MIKROBIOLOGII EPIDEMIOLOGII I IMMUNOBIOLOGII, no. 1, 1994, pages 55-59, ISSN: 0372-9311  A DATABASE BIOSIS 'Online! BIOSCIENCES INFORMATION SERVICE, PHILADELPHIA, PA, US; 17 December 1998 (1998-12-17) AULT A: "FDA approves two new hepatitis therapies." Database accession no. PREV199900076805 XP002144217 abstract & LANCET (NORTH AMERICAN EDITION), vol. 352, no. 9145, 17 December 1998 (1998-12-17), page 1996 ISSN: 0099-5355	Α	6 June 1996 (1996-06-06) page 4, line 18 - line 24 page 5, line 33 - line 36	19-23
BIOSCIENCES INFORMATION SERVICE, PHILADELPHIA, PA, US; 17 December 1998 (1998-12-17) AULT A: "FDA approves two new hepatitis therapies." Database accession no. PREV199900076805 XP002144217 abstract & LANCET (NORTH AMERICAN EDITION), vol. 352, no. 9145, 17 December 1998 (1998-12-17), page 1996 ISSN: 0099-5355	A	BIOSCIENCES INFORMATION SERVICE, PHILADELPHIA, PA, US; 1994 KOKOREVA L N ET AL: "Clinico-morphological characterization and effectiveness of interferon therapy in patients with chronic hepatitis delta." Database accession no. PREV199497368940 XP002144216 abstract & ZHURNAL MIKROBIOLOGII EPIDEMIOLOGII I IMMUNOBIOLOGII, no. 1, 1994, pages 55-59,	26
	Α	BIOSCIENCES INFORMATION SERVICE, PHILADELPHIA, PA, US; 17 December 1998 (1998-12-17) AULT A: "FDA approves two new hepatitis therapies." Database accession no. PREV199900076805 XP002144217 abstract & LANCET (NORTH AMERICAN EDITION), vol. 352, no. 9145, 17 December 1998 (1998-12-17), page 1996 ISSN: 0099-5355	27-31

In: Itional Application No PCT/US 99/30843

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C.(Continu Category *	ation) DOCUMENTS CONSIDERED TO BE RELEVANT  Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Category *	Onaudi of document, minimulcation, milete appropriate, of the relevant passages	Loughant (A Chaite 140*
A	DATABASE BIOSIS 'Online! BIOSCIENCES INFORMATION SERVICE, PHILADELPHIA, PA, US; October 1997 (1997-10) HUANG CHIU-CHING: "Hepatitis in patients with end-stage renal disease." Database accession no. PREV199800049222 XP002144218 abstract & JOURNAL OF GASTROENTEROLOGY AND HEPATOLOGY, vol. 12, no. 9-10, October 1997 (1997-10), pages S236-S241, ISSN: 0815-9319	27-31

Information on patent family members

Im: attonal Application No PCT/US 99/30843

Patent document cited in search repor	t	Publication date		atent family member(s)	Publication date
EP 0170204	A	05-02-1986	DE	3428370 A	13-02-1986
			DE	3505060 A	14-08-1986
			ĀT	67786 T	15-10-1991
		•	AU	600653 B	23-08-1990
			AU	4554985 A	06-02-1986
			BG	60445 B	31-03-1995
			CA	1340184 A	15-12-1998
			DE	3584198 A	31-10-1991
			DK	346385 A	02-02-1986
			ES	545725 D	01-08-1986
			ES	8609475 A	16-12-1986
			ES	552431 D	01-09-1987
			ES	8708013 A	16-11-1987
			FI	852956 A,B,	02-02-1986
			GR	851866 A	02-12-1985
			HK	187896 A	18-10-1996
			HU	39477 A,B	29-09-1986
			ΙE	58942 B	01-12-1993
			IL	75963 A	25-05-1992
			JP	2566909 B	25-12-1996
			JP	61181381 A	14-08-1986
			JP	2567195 B	25-12-1996
			JP	6181771 A	05-07-1994
			KR	136799 B	25-04-1998
			MX	9203645 A	01-09-1992
		•	NO	177863 B	28-08-1995
			NZ	212937 A	27-08-1991
			PT	80901 A,B	01-09-1985
			SG	134394 G	13-01-1995
			SU	1523054 A	15-11-1989
			SU	1551251 A	15-03-1990
			ZA	8505759 A	29-04-1987
		نے ہے بند ہے بیہ ہے شد یہ بانا ماہ شد شد شد شد شد مد	SU	1572419 A	15-06-1990
WO 9617063	Α	06-06-1996	US	5641665 A	24-06-1997
			EP	0795015 A	17-09-1997
			JP	10509877 T	29-09-1998